

Table of Adenovirus-p53 Clinical Trials (as of February 2002)

Treatment	Cancer	Admin	Clinical Stage	Status/Result
INGN 201	SCCHN (T302)	Intratumoral	III	Ongoing
INGN 201	SCCHN (T301)	Intratumoral (with chemotherapy)	III	Ongoing
INGN 201	NSCLC	Intratumoral (with radiation therapy)	II	Combination INGN 201 and radiation therapy appears more effective than radiation alone
INGN 201	SCCHN (T207)	Intratumoral	II	Safe
INGN201	Locally advanced primary breast	Intratumoral (with chemotherapy)	II	Study has been initiated
INGN 201	Esophageal	Intratumoral	II	Ongoing
INGN 201	SCCHN (T201)	Intratumoral	II	Safe; demonstrated clinical activity
INGN 201	SCCHN (T202)	Intratumoral (lower dose)	II	Safe; trend towards shorter survival than T201
INGN 201	Ovarian	Intraperitoneal	I	Transgene expression observed and increased expression of downstream marker; well-tolerated
INGN 201	Ovarian	Intraperitoneal (laparoscopy)	I	Well-tolerated; potentially useful clinical response
INGN 201	Bladder	Intravesical	I	Transgene expression observed; safe; ongoing
INGN 201	Advanced solid tumors (colon, breast, prostate, sarcoma,	Intravenous	I	Well tolerated at doses up to 1×10^{12} vp; accrual is ongoing to further

	NSCLC, H&N)			determine MTD; evaluation of p53 expression is pending
INGN 201	SCCHN	Intratumoral (with and without tumor resection)	I	Transgene expression and expression of downstream targets observed; safe; potentially useful clinical response
INGN 201	NSCLC	Intratumoral	I	Transgene expression and apoptosis observed; safe; potentially useful clinical response
INGN 201	NSCLC	Intratumoral (with cisplatin)	I	Expression observed; well tolerated; potentially useful clinical response
INGN 201	Prostate	Intratumoral (INGN 201 treatment prior to tumor resection)	I	Transgene expression and apoptosis demonstrated; safe
INGN 201	Glioma	Intratumoral and intracranial (stereotactic injection intratumorally, followed by tumor resection, followed by injection into tumor bed	I	Expression observed; safe; apoptosis observed; ongoing
INGN 201	Hepatocellular Carcinoma	Intratumoral	I	Study closed; 1 patient treated
INGN 201	Breast	Intratumoral (with chemotherapy)	I	Study closed; 2 patients treated

INGN 201	Bronchioloalveolar lung carcinoma	Broncho-alveolar lavage	I	Safe; potentially useful clinical response; ongoing
INGN 201	Malignant ascites	Intraperitoneal	I	Study closed; 1 patient treated
INGN 201	Colorectal	Intratumoral	I	Study closed; 6 patients treated; expression of downstream markers demonstrated
INGN 201	Lung	Intratumoral (with and without cisplatin)	I	Ongoing
INGN 201	Oral dysplasia (pre-malignant)	Intramucosal injection; oral rinse		Not started
SCH 58500	Ovarian	Intraperitoneal (with chemotherapy)	II/III	Reported closed
SCH 58500	Lung	Intratumoral (with chemotherapy)	II	Transgene expression observed; well-tolerated; enhanced local effects suggested with certain chemotherapies
SCH 58500	Ovarian	Intraperitoneal (with chemotherapy)	I/II	Well tolerated; expression observed; prolonged patient survival
SCH 58500	Lung	Intratumoral	I	Transgene expression and expression of downstream target observed; safe; transient tumor growth control
SCH 58500	Bladder	Intratumoral or intravesical (with	I	Transgene expression and expression of downstream marker

		transduction enhancer)		demonstrated after intravesical instillation
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